510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

EFS Eberle Feinwerktechnische Systeme GmbH & CO. KG
Shaver System Accessories

K092977

September 14th, 2009

SEP 29 2010

1. Submitter Information:

a. Correspondent/ Distributor:

Name:	Innovative Endoscopy Components, LLC
Address:	731-733 Shotgun Road Ft. Lauderdale, FL 33326
Telephone:	(954) 217-8780
Fax:	(954) 217-8781
E-Mail:	info@endoscopy.md
Registration No:	1064152
Owner/ Operator No:	9026517

b. Manufacturer:

Name:	EFS Eberle Feinwerktechnische Systeme GmbH & CO. KG
Address:	Glasbronnenstrasse 6 D-75449 Wurmberg GERMANY
Telephone:	(+49) 07044-9611-0
Fax:	(+49) 07044-9611-11
E-Mail:	info@efs-eberle.de
Registration No:	3005820796
Owner/ Operator No:	9086231

2. Device Name:

Classification Name:	Arthroscope and Accessories
Common Name:	Surgical Shaver and Accessories
Proprietary Name:	EBERLE Shaver System Accessories

3. Classification

Classification Number:	CFR 888.1100 Class II
Product Code:	HRX

4. Indication for use:

The EBERLE Shaver System Accessories are designed to use with the EBERLE Shaver System for arthroscopy surgical procedures like shaving, burring, abrading, cutting, drilling and resecting of fibrous tissue, cartilage tissue and bone conducted by qualified surgeons only.

5. Description of Device:

The Eberle Shaver System Accessories are manufactured by EFS Eberle Feinwerktechnische Systeme GmbH & CO. KG in Germany. They are developed for surgical use in the field of arthroscopy and should only be used by trained personnel in designated institutions.

The Eberle Single Use Shaver Blades consists of an outer tube with a hub and a rotating inner tube with a connector. The inner and outer tube consists of stainless steel. The hub and connector consist of POM, the tubes consists of stainless steel. The Blades are provided in a sterile packaging and are intended for single use (not autoclave- reusable).

The Eberle Hand Piece with Switch has three buttons to select the direction of rotation. It consists of Stainless Steel and Aluminum.
The Eberle Drill- and the Saw- Hand Piece also consist of Stainless Steel and Aluminum. The Drill has two buttons to select the direction of rotation and the Saw hast a operator lever.

All these components are designed, constructed and intended to be operated exclusively as a unit with the Eberle Shaver System C2.

6. Substantial Equivalence:

K061134, Eberle Shaver System C2 and Shaver Blades
K032117, Stryker Total Performance System Shaver
K030009, KSEA Powershaver System S2
K990524, Linvatec E9000 System
K002523, Linvatec Advantage Drive System
K072706, Linvatec Handpiece System
K080617, Richard Wolf Power Driver ART1

7. Description of Safety:

- EMC according IEC 60601-1-2 for not life supporting group 1, class B equipment
- Electrical safety according EN 60601-1 / IEC 601-1
- DIN EN 12011:1998 Instrumentation to be used in association with non-active surgical implants - General requirements
- Recommendation of the Commission for Hospital Hygiene and Infection Prevention of the Robert Koch Institute (RKI) and the Federal Institution for Drugs ad Medical Devices (BfArM. Hygiene requirements in processing medical products. Federal Health Publication 44 (2001). 1115-1126
- DIN EN 556-1 Sterilization of medical devices
- DIN EN ISO 17664 Sterilization of medical devices
- DIN EN ISO 11138-3 Sterilization of health care products
- DIN EN ISO 11737 Sterilization of medical devices
- EN ISO 11607 Packaging for terminally sterilized medical devices

The selection of the materials for the EBERLE Shaver System Accessories has been determined through demonstrated appropriate levels of biocompatibility. The materials are similar or identical to those used for predicate devices as well as other brands legally sold in the United States.

8. Summary:

Biocompatibility, function, indications and designs have been developed to ensure the safety of this device and it is substantially equivalent to commercially approved shaver systems and accessories available for sale in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

EFS Eberle Feinwerktechnische Systeme
% Innovative Endoscopy Components, LLC
Mr. Gerald Goigitzer
Managing Director
731-733 Shotgun Road
Ft. Lauderdale, Florida 33326

SEP 29 2010

Re: K092977
Trade/Device Name: EBERLE Shaver System Accessories
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: September 20, 2010
Received: September 22, 2010

Dear Mr. Goigitzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K092977**

SEP 29 2010

Device Name: EBERLE Shaver System Accessories

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Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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